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**Notice of Allowability**

Application No.	Applicant(s)	
09/942,941	MIEKKA ET AL.	
Examiner	Art Unit	
Johnnie L. Smith II	2881	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to response to detailed office action filed 07/24/2006.
2.  The allowed claim(s) is/are 98-132.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.



DAVID VANORE  
PRIMARY PATENT EXAMINER

## **DETAILED ACTION**

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gregory Lowen on 11/09/2006.

The application has been amended as follows:

Claim 100: A method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation comprising reducing the temperature of said preparation to a level effective to protect said preparation from gamma irradiation; and irradiating said preparation with gamma radiation at a rate of greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation.

Claims 133-135 are canceled.

***Allowable Subject Matter***

2. Claims 98-132 are allowed.
3. The following is an examiner's statement of reasons for allowance: the prior art searched and cited failed to teach or fairly suggest a method for inactivating at least one biological contaminant or pathogen in a preparation containing albumin having a step of irradiating said preparation with gamma radiation at a rate of greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation as disclosed in claim 98.
4. The prior art searched and cited failed to teach or fairly suggest a method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation having a step of irradiating said preparation with gamma radiation at a rate greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation as disclosed in claim 99.
5. The prior art searched and cited failed to teach or fairly suggest a method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation having a step of reducing the temperature of said preparation to a level effective to protect said preparation from gamma irradiation; and

irradiating said preparation with gamma radiation at a rate of greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation as disclosed in claim 100. All remaining dependant claims are allowable because of their dependences. The method of sterilizing biological contaminants is old in the art, but none of the searched and cited references to another, teach the use of a does rate greater than 3.0 kGy/hr.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnnie L. Smith II whose telephone number is 571-272-2481. The examiner can normally be reached on Monday-Thursday 6-4 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571.272.2312. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Johnnie L Smith II  
Examiner  
Art Unit 2881

  
DAVID VANORE  
PRIMARY PATENT EXAMINER

  
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